Veeva SiteVault: Use of Certified Copy

Purpose:

To establish standard processes and procedures for the use of Certified Copy at VCU.

Scope:

This procedure applies to activities and essential documents required for the conduct of research at VCU.

Users of this system will be the investigator and investigator delegates, including site administrative and operations personnel.

This procedure does not apply to source or clinical information captured in system such as an electronic health record, Institutional Review Board (IRB) or review committee system, or clinical trial management system.

This procedure does not apply to federal or state regulatory activities captured in another system such as financial conflict of interest (FCOI) reporting as required by the National Science Foundation (NSF) and the Public Health Service (PHS)[1].

Certified Copy procedures will be performed by site personnel including, investigator and investigator delegates, site administrative and operations personnel.

This process does comply with Virginia's law 42.1 related to records management and does not require an RM-3 to be completed. Please note if there is a pending or active records hold, all copies whether official or certified versions must be maintained until the hold is lifted. Prior to creating certified copies within Veeva SiteVault, confirm that there is no contractual language in your clinical trial contract that does not allow certified copies or that your individual department does not have a policy in place prohibiting this.

Responsibility:

VCU personnel will be responsible for both performing and complying with this SOP and assuring the appropriate personnel are trained on this SOP.

Definitions:

Certified Copy: A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original[2].

eISF: electronic Investigator Site File. The computer system used to house *Essential Documents* required for the conduct of clinical research by the investigator.

Essential Documents: Those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to

[1] 42 CFR § 50.605. Management and reporting of financial conflicts of interest.

[2] Integrated Addendum to ICH EC(ER) Guideline for Good Clinical Practice E6(R2). 1.63 Certified Copy.

demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements. Often referred to as regulatory documents[3].

FCOI: Financial conflict of Interest

IRB: Institutional Review Board

ISF: Investigator Site File. The investigator site file includes all Essential Documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced by the investigator. These documents serve to demonstrate the compliance of the investigator with the standards of Good Clinical Practice and with all applicable regulatory requirements. The ISF does not include the full scope of Trial Master File documents which apply to the sponsor role in research.

NSF: National Science Foundation

PHS: Public Health Service

PHI/PII: Protected Health Information/ Personally Identifiable Information

Source Data: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).[4]

Source Documents: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and medico-technical departments involved in the clinical trial).[5]

Validation of Computer Systems: A process of establishing and documenting that the specified requirements of a computerized system can be consistently fulfilled from design until decommissioning of the system or transition to a new system. The approach to validation should be based on a risk assessment that takes into consideration the intended use of the system and the potential of the system to affect human subject protection and reliability of trial results.[6]

Background

A certified copy is a paper or electronic copy of the original document that has been verified by a dated signature or generated through a validated process to produce an exact copy having all the same information, including data that describe the context, content and structure, as the original.

The ICH GCP guidelines require that copies (irrespective of the media used) in the Investigator Site File that irreversibly replace originals should be certified copies of the original. Any transfer or

[3] ICH-GCP E6(R2), 2016. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice. 1.23 Essential Documents

[4] ICH-GCP E6(R2), 2016. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice. 1.51 Source Data

[5] ICH-GCP E6(R2), 2016. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice. 1.52 Source Documents

[6] ICH-GCP E6(R2), 2016. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice. 1.65 Validation of Computer Systems

conversion (e.g. digitization or printing), which does not fulfil the criteria for a certified copy, is not suitable to replace an original file. Redacted documents are not considered to be certified copies.

Procedure

Essential documents which are originated or finalized outside of the eISF system may be certified as an exact copy in the eISF system, thus allowing for the destruction of the paper version. This applies to regulatory and essential documents. For source documents and data, refer to VCU's policy on source document and data capture.

The process for risk-based Quality Control (QC) checks for certified copies before destruction of the originals should ensure that the copy is of sufficient quality for the intended purpose and should include the following attestation by the person certifying the copy:

- congruency of the information contained between original and certified copy
- accuracy of the metadata attributed to the document
- accuracy of file name; including that it is marked as an updated version of an already existing document
- quality of the image (suitable resolution to allow readability as per the original, legibility and reproduction of color (when applicable) and legibility of wet-ink signatures or annotations and handwriting in general etc. (when applicable)
- audit trail associated with the document (when applicable)
- approval of the certification process (when applicable)

The person who certifies the copy as an accurate and complete representation of the original, having all of the same attributes and information, is the same person who made the copy from the original.

Redacted Documents

Redacted documents are not considered certified copies per ICH-CGP or FDA definitions. FDA does not have a specific term used to describe the redacted copies for source documents.[7]

References

- FDA E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)
- FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, 2007
- FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, 2013
- CFR Title 21, Part II
- FDA Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers, 2023
- Veeva SiteVault Validation Documents

[7] ICH-GCP E6(R2), 2016. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice 4.9 Reports and Records.

Contact

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Revision/Change History

Date	Version	Change History
02/22/2023	1.0	Initial
03/29/2023	2.0	Added contact information
12/11/2023	3.0	Fixed broken links
12/03/2024	4.0	Fixed broken links and typographical error